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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,911	12/18/2001	Kit Yeng Lim	SBI-100	4817
45488	7590	10/03/2005	EXAMINER	
WILLIAMS, MORGAN & AMERSON, P.C./ZIMMER 10333 RICHMOND, SUITE 1100 HOUSTON, TX 77042			RAMANA, ANURADHA	
			ART UNIT	PAPER NUMBER
			3732	

DATE MAILED: 10/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/023,911	LIM ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Anu Ramana	3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 18 July 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-8, 10-17, 19-28, 30-33, 35 and 37 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-8, 10-17, 19-28, 30-33, 35 and 37 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 12/18/2001 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-4, 6, 10-11, 13-14, and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Michelson (US 6,537,320).

Michelson discloses an implant or plug 20 made of a bioresorbable or "biodegradable" material such as polylactone ("polymer") having a hollow portion or "bore" 42 containing bone growth inducing or promoting material and fins or "threads" or "at least one annulus engaging member" (36, 36') on its outer surface wherein the plug is sealed at one end by a cap or "sealing member" 46 having a slot to engage a driver or tool for inserting and rotating implant 20 into disc space (Figures 1, 2A, 2E, 16A and 16B, col. 11, lines 16-26, col. 12, lines 30-51, col. 13, lines 24-60, col. 15, lines 59-67 and col. 16, lines 1-31).

Michelson also discloses a plurality of openings or "apertures" 38, 38' on the upper and lower walls 30, 30', passing through the body and in communication with bore 42 (col. 12, lines 62-67 and col. 13, lines 1-23.)

Claims 1-3, 6, 10-11, 13 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Boyer, II et al. (US 6,767,369).

Boyer, II et al. disclose a plug for filling vacancies or defects in bone tissue having an external ribbing 36 or "at least one annulus engaging member," a cap and a slot 38 in the cap. Boyer, II et al. also disclose another embodiment of plug having at least one annulus engaging member 286 and apertures 284. The Boyer, II et al. plugs

may be formed using resorbable or "biodegradable material" and filled with bone growth materials (Figs 1A-1J, 3N, col. 3, lines 66-67, col. 4, lines 1-56, col. 8, lines 31-59, col. 9, lines 8-65, col. 10, lines 47-67, col. 11, lines 1-67 and col. 12, lines 1-45).

Claims 19, 20, 21, 25-28, 30-33 and 37 are rejected under 35 U.S.C. 102(e) as being anticipated by Bao et al. (US 6,224,630).

Bao et al. disclose a method of sealing an annular defect utilizing a porous plug made of a biodegradable material such as polycaprolactone wherein the plug can have one or more expanded end portions or "at least one annulus engaging member" to prevent migration of the plug and wherein the annulus engaging member does not engage vertebrae (Fig. 2, col. 5, lines 31-47, col. 6, lines 13-40, col. 7, lines 61-67 and col. 8, lines 1-9). Bao et al. also disclose that their plug can contain growth promoting substances such as growth factors, immune system suppressors etc. in discrete portions (or "growth promoting matrix") thereof (col. 9, lines 12-67 and col. 10, lines 1-56).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5, 7-8, 12, 15, 17 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson (US 6,537,320) in view of Boyce et al. (US 6,294,187).

Regarding claims 5, 15 and 26, Michelson does not disclose specific types of biodegradable polymers.

Regarding claims 7-8, 12, 17, 21, 27 and 28, Michelson does not disclose specific types of bone growth materials.

Boyce et al. teach biodegradable polymers such as polylactic-co-glycolic acid, polycaprolactone, polycyanoacrylates etc. (col. 8, lines 23-40).

Boyce et al. also teach the use of bioactive substances such as antibiotics, living cells, peptides, growth factors such as TGF-beta, bone morphogenetic proteins (BMPs), angiogenic agents etc. (col. 9, lines 31-67) in an implant.

Further, regarding claim 35, Boyce et al. teach shaping an osteoimplant to assume a determined configuration to custom fit a bone repair site with precision (col. 14, lines 6-50).

Accordingly it would have been obvious to one of ordinary skill in the art at the time of the invention to have made the Michelson implant of a biodegradable polymer, as taught by Boyce et al. to make the Michelson implant biodegradable. Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the bioactive substances taught by Boyce et al. in the Michelson implant to promote bone growth and to have shaped the Michelson implant to custom fit a repair site.

Claims 4-5, 7-8, 12, 14, 15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyer, II et al. (US 6,767,369) in view of Boyce et al. (US 6,294,187).

Regarding claims 4, 5 and 15, Boyer, II et al. disclose all elements of the claimed invention except for resorbable materials such as biodegradable polymers.

Regarding claims 7-8, 12 14, 15 and 17, Boyer, II et al. do not disclose specific types of bone growth materials.

Boyce et al. teach biodegradable polymers such as polylactic-co-glycolic acid, polycaprolactone, polycyanoacrylates etc. (col. 8, lines 23-40).

Boyce et al. also teach the use of bioactive substances such as antibiotics, living cells, peptides, growth factors such as TGF-beta, bone morphogenetic proteins (BMPs), angiogenic agents etc. to accelerate the ingrowth of new bone tissue in an implant (col. 9, lines 31-67).

Accordingly it would have been obvious to one of ordinary skill in the art at the time of the invention to have made the Boyer, II et al. implant of a biodegradable polymer, as taught by Boyce et al. to make the Boyer, II et al. implant biodegradable. Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the bioactive substances taught by Boyce et al. in the Boyer, II et al. implant to promote bone growth.

Claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bao et al. (US 6,224,630) in view of Boyer, II et al. (US 6,767,369).

Bao et al. disclose all elements of the claimed invention except for a sealing member or cap at one end of the plug and a slot in the cap.

Boyer, II et al. teach a type of biodegradable plug for filling bony defects including a sleeve and a cap with a slot (Fig. 3N, col. 3, lines 66-67, col. 4, lines 1-56, col. 8, lines 31-59, col. 9, lines 8-65, col. 10, lines 47-67, col. 11, lines 1-67 and col. 12, lines 1-45).

It would have been obvious to one of ordinary skill in the art to substitute a plug as, for example, taught by the Boyer, II et al. reference for the plug of the Bao et al. wherein so doing would amount to mere substitution of one functionally equivalent plug for another within the same art and the selection of any of these plugs would work equally well in the claimed method.

The claimed method steps are rendered obvious by the above discussion.

### ***Response to Arguments***

Applicant's arguments filed on July 18, 2005 have been fully considered but they are not persuasive.

Regarding Applicant's arguments that Michelson does not anticipate claims 1-4, 6, 10-11, 13-14, 16, 19-20, 22-25 and 30-33 and that Boyer, II et al. do not anticipate claims 1-2, 6, 10-11 and 16, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations.

*Ex parte Masham*, 2 USPQ2d 1647 (1987). In the instant case, the Michelson implant and the Boyer, II et al. plug meets all of the claimed structural limitations and thus anticipate Applicant's claimed invention.

Applicant's arguments with respect to the rejections of claims 19-23, 25-28, 30-33 and 37 under 35 U.S.C. 103(a) as being unpatentable over "Bao et al. (US 6,224,630) in view of Michelson (US 6,537,320)" are not pertinent to the rejections of record, namely, "Bao et al. (US 6,224,630) in view of Boyer, II et al. (US 6,767,369)."

### **Conclusion**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

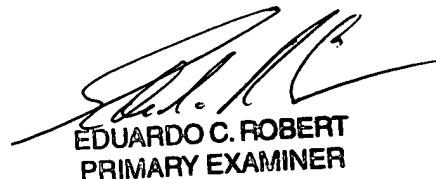
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AR *Anuradha Ramana*  
September 26, 2005



EDUARDO C. ROBERT  
PRIMARY EXAMINER